

AUG - 7 2003

K03158
Page 1 of 2



Nucletron

NUCLETRON B.V.

Waardgelder 1 3905 TH Veenendaal
P.O.Box 930 3900 AX Veenendaal
The Netherlands
Phone +31 318 557133
Fax +31 318 550485

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
as required by section 807.92(c)

Submitter of 510(k):

Company name: Nucletron Corporation
Registration number: 1121753
Address: 7080 Columbia Gateway Drive
Columbia, MD 21046-2133
Phone: 410-312-4100
Fax: 410-312-4197
Correspondent: Lisa Dimmick
Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name: Swift 2.0
Common/Usual Name: Radiation Therapy Planning System
Classification Name: Accessory to Radiotherapy Device
Classification: 21Cfr892.5050 Class II

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Real Time HDR	K022739

Description:

Swift is a "real time" treatment planning system for brachytherapy especially meant for treatment of cancer in the prostate. Direct 3D Ultrasound imaging of the treatment gives the physician the possibility to update the planning of the dwell positions of the source in the prostate of the patient.

K022739
Page 30 of 32

The program provides a variety of plan evaluation tools to assist in generating the most optimal dose distribution, i.e. dose volume histograms, dose verification points and dose profiles. The software program provides the physician with anatomical and dosimetric information, to determine the positioning and loading of the radioactive sources, prior to radiation treatment. The program also provides the treatment time and dose distribution for the specified loading. From this the information the patient can be treated with the dwell positions of the source.

Modifications to the previously cleared device K022739, have been made to add functionality for:

- Encoder
- 3D Ultrasound acquisition
- 3D VOI contouring
- 3D Catheter recognition
- Inverse Plan

The modified device is an accessory to an afterloader. The program consists of two modules:

- Treatment Planning Software: Swift
- Database: Smoothbase

The software runs on a Windows XP platform.

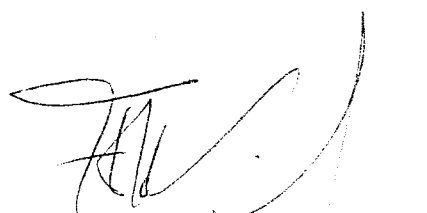
Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

Swift is a software application intended for use with Brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal, involving afterloading radioactive sources.

Summary of technological considerations:

Swift is substantially equivalent to the cleared predicate device, Real Time HDR, 510(k)#: K022739.



Name: Frits van Krieken
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

2-4-2003

Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K031158
Trade/Device Name: Swift 2.0
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled
radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: July 14, 2003
Received: July 16, 2003

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k)
Number

K031158

Device Name

Swift 2.0

Indications for
Use

Swift is a software application for Brachytherapy Treatment Planning, for the treatment of cancer, i.e. intercavitary, interstitial, intraluminal, involving radioactive sources.

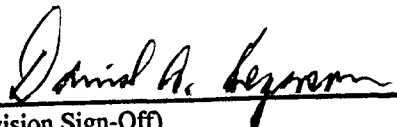
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031158